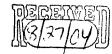


Ortho Molecular Products Inc 3017 Business Park Drive PO Box 1060 Stevens Point, WI 54481 715 342 9881 Phone 800 332 2351 715 342 9866 Fax orthomolecular products com

Office of Special Nutritional (HFS-450) Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835



Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached label).

Name of Manufacturer: Ortho Molecular Products, Inc.

3017 Business Park Drive

P.O. Box 1060

Stevens Point, WI 54481

Statement Text: Thyrotain

**Dietary Ingredients:** Iodine (from Kelp, Potassium), L-Tyrosine USP, Ashwaganda Root Extract (Standardized to contain 15% Withanolides), Bladderwrack Leaf, Ascorbyl Palmitate, Microcrystalline Cellulose, and Silicon Dioxide.

Dietary Supplement Name: Thyrotain

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

mandi 8-23-04

Sincerely,

Deborah Zurawski

Quality Assurance Manager Ortho Molecular Products 975 0162

LET

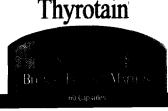
14574

Suggested Use As a dietary supplement, take 1-2 capsules per day or as recommended by your health care professional Formulated to be free of the following Gluten, egg, dairy peanuts, soy, yeast, artificial colors and flavors

Do not consume this product if you are pregnant or nursing. Consult your physician for further information. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion. Keep container tightly closed. Store at room temperature. Keep our of reach of children. Label ID L. 0MP100-620060. 4









Amount Per % Daily
1 capsule contains Serving Value
1 cdine (from Kelp, Potassium) 150 mcg 100%
L-Tyrosine USP<sup>III</sup> 500 mg Ashwaganda Root Extract 100 mg (Standardized to contain 15% Withanolides)
Bladderwrack Leaf 50 mg \* % Daily Value not established

This product was sealed by your protection. Do not use if outer looped next seal or more seal is missing or barraged This stander last of leas reduced by the first and long Admission. This product is of medicil to disprise test one in preed as disease. Milig by Orthio Molecular Products, Inc. 3017 Business Park Drive Stevens Point, Wil 54481

hthoMolecularProducts.co